



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/SE87/00201</p> <p>(22) International Filing Date: 21 April 1987 (21.04.87)</p> <p>(31) Priority Application Number: 8601815-7</p> <p>(32) Priority Date: 18 April 1986 (18.04.86)</p> <p>(33) Priority Country: SE</p> <p>(71)(72) Applicant and Inventor: LUNDGREN, Dan [SE/SE]; Kyrkvägen 5, S-430 80 Hovås (SE).</p> <p>(74) Agents: STRÖM, Tore et al.; Ström & Gulliksson AB, Box 4188, S-203 13 Malmö (SE).</p> <p>(81) Designated States: AT (European patent), AU, BE (European patent), BR, CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent),</p>		<p>NL (European patent), NO, SE (European patent), SU, US.</p> <p>Published <i>With international search report.</i> <i>With amended claims.</i> <i>In English translation (filed in Swedish).</i></p>
<p>(54) Title: IMPLANT PASSAGEWAY</p> <div data-bbox="444 1243 1208 1654" data-label="Image"> </div> <p>(57) Abstract</p> <p>Implant passageway for connection of body cavities or body vessels to a device, container or the like externally of the body. It comprises an element (11) which consists of a biocompatible material or has a biocompatible outside layer. This element forms a socket (13) with a through passage (14) and on the outside of the curved surface thereof inwardly of an end portion (15) having a smooth outside surface, forms radial flanges (16) mutually spaced axially and defining between radial surfaces thereof peripheral grooves for growth of surrounding tissue thereinto.</p>		

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IMPLANT PASSAGEWAY

5 The invention relates to an implant passageway for connection of body cavities or body vessels to a device, container or the like externally of the body, comprising an element which consists of a biocompatible material or has a biocompatible outside layer and which includes a socket with a through passage.

10 Such an implant passageway can be used e.g. for establishing a permanent connection to the abdomen of persons who from time to time have to be subject to e.g. peritoneal dialysis, or for establishing a temporary connection to a body cavity. The difficulty when
15 arranging an implant passageway is above all that the epithelium cells grow along the passageway, rejection from the body being the consequence thereof.

This difficulty is overcome by the implant passageway of the invention having obtained the characteristics of claim 1.

20 In order to explain the invention in more detail an embodiment thereof will be described below, reference being made to the accompanying drawing in which

25 FIG. 1 is a fragmentary axial sectional view of an implant passageway of the invention in one embodiment thereof,

FIG. 2 is a perspective view on a reduced scale of the element of the implant passageway of FIG. 1 which is to be positioned partly under the skin,
30 FIG. 3 is a perspective view showing the implanted passageway,

FIG. 4 is a fragmentary axial sectional view of another embodiment of the implant passageway,
FIG. 5 is a fragmentary axial sectional view of a
35 FIG. 6 is a perspective sectional view of the

implant passageway of FIGS. 1 to 3 slightly modified.

In the embodiment of FIGS. 1, 2, and 3, the implant passageway comprises an element 10 which is to be implanted in the tissue under the skin. This element should be made of a biocompatible material or should at least be coated with such material on the surface thereof. The material can be a metal or a metal alloy. The preferred metal is titanium, but also aluminium, indium, zirkonium and molybdenum can be used in this connection, and suitable alloys can contain cobalt-nickel-chromium, cobalt-chromium-molybdenum, or aluminium-vanadium-titanium. Also biocompatible polymers can be used such as polyethylene, silicone, or polyurethane of the highest medical quality. When the element is coated with one of the metals or metal alloys mentioned above on the outside thereof, the coating can be made by evaporation in vacuum and can have a thickness of the order of 50 to 300 nm.

The element 10 comprises a circular base plate 11 having through apertures 12. On the base plate, a central socket 13 is provided which forms a through cylindrical passage. The socket projects from the upper side of the plate 11 and the outer end of the socket can be shaped for connection e.g. to a hose, or for connection to a container, a plastic bag, a syringe, or any other device. Adjacent the outer end the socket has a portion 15 having a smooth curved surface. Said portion tapers slightly towards the outer end and has curved end edges, a number of flanges 16 with apertures 17 being arranged inwardly of portion 15. The flanges are spaced radially from each other and define peripheral grooves between radial surfaces. At the outer edge the base plate 10 has a circumferential apertured fence 18 which is thus spaced from the socket 13 so that

there is provided on the upper side of the base plate an annular free zone 19 between the socket and the fence. The fence as shown here forms a ring supported by uprights, and this ring can have round cross-sectional shape as in FIG. 1 or square cross-sectional shape as in
5 FIG. 2.

When the element 10 is implanted on a human being or on an animal, portion 15 of the socket 13 extends through the epithelium layer 20, the flanges 16, the
10 base plate 11, and the fence 18 being located under the epithelium layer. Then, the connective tissue around the element can grow into the space between the flanges 16 and through the apertures 17 therein, and it can also grow through the apertures 12 in the base plate 11 and
15 around the fence 18 as has been indicated by arrows in FIG. 1. The epithelium 20 grows downwards along the smooth end portion 15 but will then be stopped by the growth of connective tissue taking place below this portion. Thus, in the region between the socket and the
20 fence connective tissue will be present, region 19 forming an (immobilized) zone relieved from external stretching of the skin by the fence boundary. Said zone is indicated by a dot-and-dash line 19' in FIG. 3. By this arrangement the element 10 will be firmly fixed in
25 the connective tissue, avoiding mechanically induced irritation-inflammation around the socket 13 which projects from the tissue through the epithelium. In FIG. 3, it is illustrated how a catheter 21 is connected to the implant passageway.

30 In order to fix the element during healing a round or star-shaped plastic disk 22 e.g. of polytetrafluoro ethylene or another hydrofobic plastic material can be secured to the socket 13 by means of a screw 23 and an intermediary washer 24, the passage 14 being internally
35 threaded of course. The disk 22 engages the outside of

the skin in the region of the fence 18 and can be pressed more or less heavily against the epithelium layer 20 by tightening the screw 23. This disk can be left on the socket also after completion of the healing.

5 In order to achieve a satisfactory growth of connective tissue into the flanges 16 it has been found suitable to have a spacing of the flanges which is at least 0.08 mm and to have a depth of the groove between adjacent flanges which is at least 0.08 mm.

10 The flanges can form a beaded edge supplementing the apertures 17 or replacing such apertures so that there is provided between adjacent flanges an undercut groove which the tissue can grow into.

15 In the embodiment of FIG. 4, the socket is surrounded by a net envelope 25 spaced from the curved surface of the socket. Connective tissue can grow through this net envelope to anchor the element 10, the flanges on the socket being provided as spacers for the net envelope.

20 In the embodiment of FIG. 5, the flanges 16 form apertures therein and axially extending rods 26 are passed through these apertures so that the connective tissue can grow into the grooves between the flanges around the rods 26 extending across the grooves.

25 The socket 13 and the fence 18 can project from one and the same side of the base plate 11 as shown in the drawing but they can also project from both sides of the base plate.

30 In the embodiment of FIG. 6, the fence 18 is supported by radial arms 27 projecting from a peripheral flange 28 on the socket 13. A hose connection 29 is passed through the socket.

CLAIMS

1. Implant passageway for connection of body cavities or body vessels to a device, container or the like externally of the body, comprising an element (10) which consists of a biocompatible material or has a biocompatible outside layer and which includes a socket (13) with a through passage (14),
c h a r a c t e r i z e d in that the socket (13) on the outside of the curved surface thereof inwardly of an end portion (15) having a smooth outside surface forms radial flanges (16) mutually spaced axially and defining between radial surfaces thereof peripheral grooves for growth of surrounding tissue thereinto.
2. Implant passageway as in claim 1,
c h a r a c t e r i z e d in that the curved surface of the flanges (16) is substantially flush with the curved surface of the smooth end portion (15).
3. Implant passageway as in claim 1 or 2,
c h a r a c t e r i z e d in that the flanges (16) form apertures (17).
4. Implant passageway as in claim 3,
c h a r a c t e r i z e d in that rods (26) are passed axially through the apertures (17) in the flanges (16).
5. Implant passageway as in claim 1,
c h a r a c t e r i z e d in that a net envelope (25) is provided around the socket (13), supported by the flanges (16).
6. Implant passageway as in any of claims 1 to 5,
c h a r a c t e r i z e d in that the element (10) comprises also a peripherally surrounding apertured fence (18) spaced radially from the socket (13).
7. Implant passageway as in claim 6,
c h a r a c t e r i z e d in that the fence (18) is arranged on a plate (11) on the element.
8. Implant passageway as in claim 7,

c h a r a c t e r i z e d in that the plate (11) forms through apertures (12).

5 9. Implant passageway as in claim 6 or 7,
c h a r a c t e r i z e d in that the socket (13) is located centrally on the plate (11) and that the socket and the fence (18) project from one end and the same side of the plate.

10 10. Implant passageway as in claim 1,
c h a r a c t e r i z e d in that the biocompatible material or the biocompatible surface layer comprises a biocompatible metal, e.g. titanium, aluminium, indium, zirkonium or molybdenum, or a biocompatible metal alloy, e.g. containing cobalt-nickel-chromium, cobalt-chromium-molybdenum, or
15 aluminium-vanadium-titanium.

20 11. Implant passageway as in claim 1,
c h a r a c t e r i z e d in that the biocompatible material comprises a polymer, e.g. polyethylene, silicone, or polyurethane.

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AMENDED CLAIMS

[received by the International Bureau on 07 September 1987 (07.09.87);
original claims 6 to 9 amended and replaced by new claims 6-10; other
claims unchanged (2 pages)]

1. Implant passageway for connection of body
cavities or body vessels to a device, container or the
like externally of the body, comprising an element
5 (10) which consists of a biocompatible material or has
a biocompatible outside layer and which includes a
socket (13) with a through passage (14), c h a r a c -
t e r i z e d in that the socket (13) on the outside
of the curved surface thereof inwardly of an end por-
10 tion (15) having a smooth outside surface, forms radial
flanges (16) mutually spaced axially and defining
between radial surfaces thereof peripheral grooves for
growth of surrounding tissue thereinto.
2. Implant passageway as in claim 1,
15 c h a r a c t e r i z e d in that the curved surface
of the flanges (16) is substantially flush with the
curved surface of the smooth end portion (15).
3. Implant passageway as in claim 1 or 2,
c h a r a c t e r i z e d in that the flanges (16)
20 form apertures (17).
4. Implant passageway as in claim 3,
c h a r a c t e r i z e d in that rods (26) are passed
axially through the apertures (17) in the flanges (16).
5. Implant passageway as in claim 1,
25 c h a r a c t e r i z e d in that a net envelope (25)
is provided around the socket (13), supported by the
flanges (16).
6. Implant passageway as in any of claims 1 to 5,
c h a r a c t e r i z e d in that the socket (13) is
30 provided with a radially projecting plate.
7. Implant passageway as in claim 6,
c h a r a c t e r i z e d in that the plate (11) forms
through apertures (12).
8. Implant passageway as in claim 6 or 7,
35 c h a r a c t e r i z e d in that the element (10)

comprises also a peripherally surrounding apertured fence (18) spaced radially from the socket (13).

5 9. Implant passageway as in claim 6, characterized in that the fence (18) is arranged on the plate (11).

10 10. Implant passageway as in claim 8, characterized in that the socket (13) is located centrally on the plate (11) and that the socket and the fence (18) project from one and the same side of the plate.

15 11. Implant passageway as in claim 1, characterized in that the biocompatible material or the biocompatible surface layer comprises a biocompatible metal, e.g. titanium, aluminium, indium, zirconium or molybdenum, or a biocompatible metal alloy, e.g. containing cobalt-nickel-chromium, cobalt-chromium-molybdenum, or aluminium-vanadium-titanium.

20 12. Implant passageway as in claim 1, characterized in that the biocompatible material comprises a polymer, e.g. polyethylene, silicone, or polyurethane.

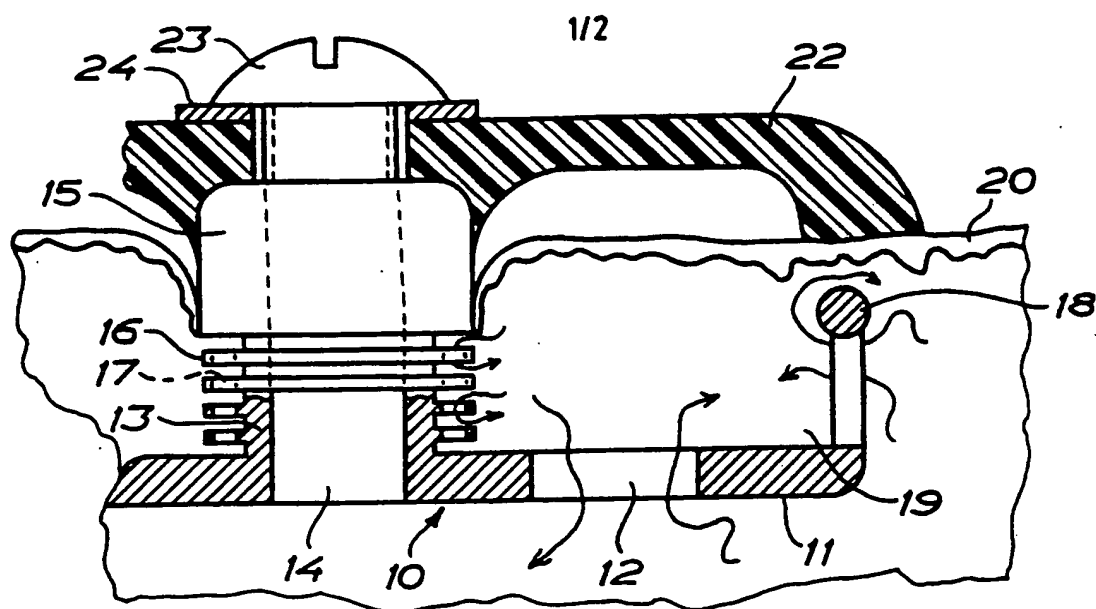


FIG. 1

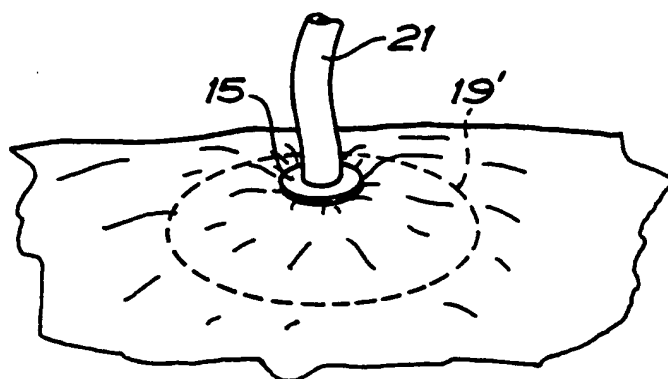


FIG. 3

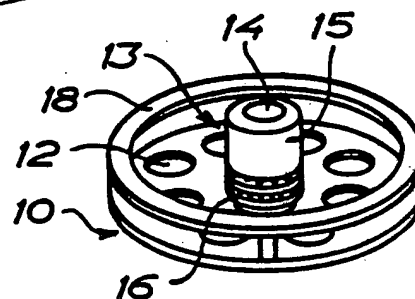


FIG. 2

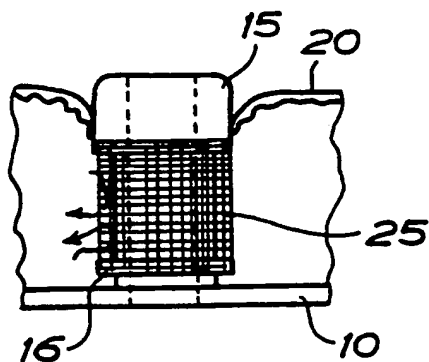


FIG. 4

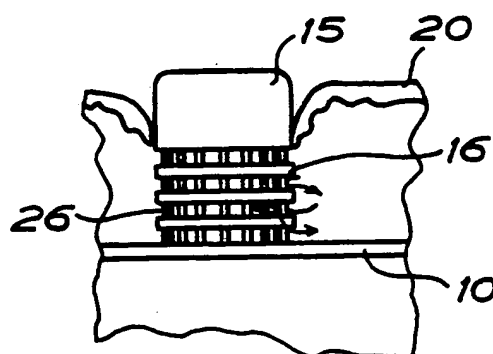


FIG. 5

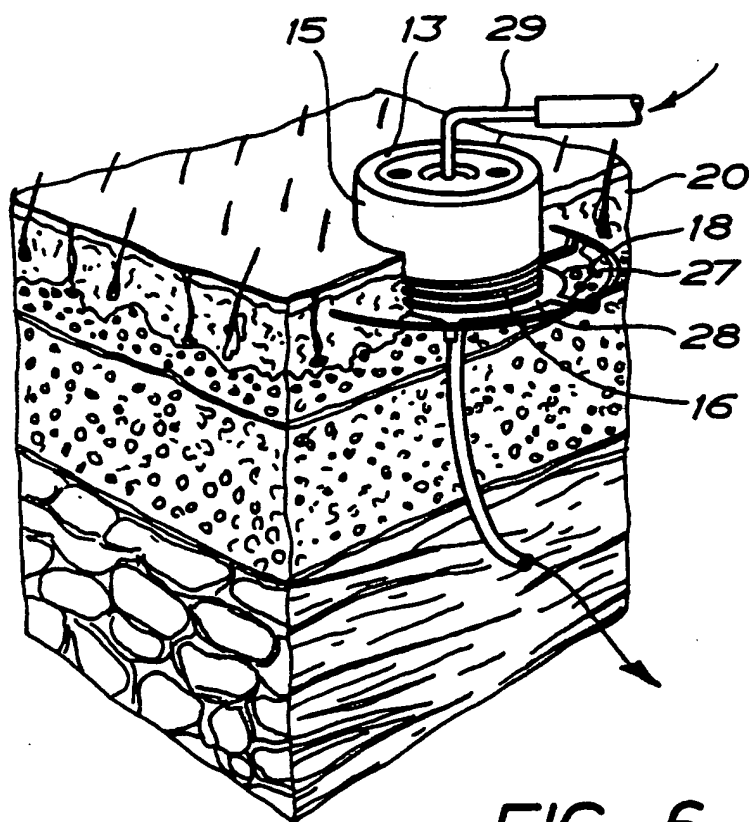


FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No PCT/SE87/00201

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) * According to International Patent Classification (IPC) or to both National Classification and IPC 4 A 61 F 2/02, A 61 F 5/44																	
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Minimum Documentation Searched 7</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%; border-bottom: 1px solid black;">Classification System</th> <th style="border-bottom: 1px solid black;">Classification Symbols</th> </tr> <tr> <td style="padding: 5px;">IPC 3 US C1</td> <td style="padding: 5px;">A 61 F 1/00, 2/00-/06, 5/44 3:1; 128:283</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched 8</div> <p style="text-align: center; padding: 10px 0;">SE, NO, DK, FI classes as above</p>			Classification System	Classification Symbols	IPC 3 US C1	A 61 F 1/00, 2/00-/06, 5/44 3:1; 128:283											
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IPC 3 US C1	A 61 F 1/00, 2/00-/06, 5/44 3:1; 128:283																
III. DOCUMENTS CONSIDERED TO BE RELEVANT * <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%; border-bottom: 1px solid black;">Category 9</th> <th style="width: 70%; border-bottom: 1px solid black;">Citation of Document, 11 with indication, where appropriate, of the relevant passages 12</th> <th style="width: 20%; border-bottom: 1px solid black;">Relevant to Claim No. 13</th> </tr> <tr> <td style="vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">DE, A, 2 948 949 (BENTLEY LABORATORIES INK.) 26 March 1981 & GB, 2056282 JP, 56028752 FR, 2474316 CA, 1144705</td> <td style="vertical-align: top; padding: 5px;">1-2</td> </tr> <tr> <td style="vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">DE, A, 2 645 990 (GENERAL ATOMIC CO.) 21 April 1977</td> <td></td> </tr> <tr> <td style="vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">GB, A, 2 143 740 (BENTLEY LABORATORIES INC.) 20 February 1985</td> <td></td> </tr> <tr> <td style="vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">US, A, 4 217 664 (FASO J.) 19 August 1980</td> <td></td> </tr> </table>			Category 9	Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13	X	DE, A, 2 948 949 (BENTLEY LABORATORIES INK.) 26 March 1981 & GB, 2056282 JP, 56028752 FR, 2474316 CA, 1144705	1-2	A	DE, A, 2 645 990 (GENERAL ATOMIC CO.) 21 April 1977		A	GB, A, 2 143 740 (BENTLEY LABORATORIES INC.) 20 February 1985		A	US, A, 4 217 664 (FASO J.) 19 August 1980	
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<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: 10</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 50%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>																	
IV. CERTIFICATION <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; padding: 5px;">Date of the Actual Completion of the International Search</td> <td style="width: 50%; border-bottom: 1px solid black; padding: 5px;">Date of Mailing of this International Search Report</td> </tr> <tr> <td style="padding: 5px;">1987-07-01</td> <td style="padding: 5px; text-align: center;">1987-07-08</td> </tr> <tr> <td style="border-bottom: 1px solid black; padding: 5px;">International Searching Authority</td> <td style="border-bottom: 1px solid black; padding: 5px;">Signature of Authorized Officer</td> </tr> <tr> <td style="padding: 5px;">Swedish Patent Office</td> <td style="padding: 5px;">Sune Söderling <i>[Signature]</i></td> </tr> </table>			Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	1987-07-01	1987-07-08	International Searching Authority	Signature of Authorized Officer	Swedish Patent Office	Sune Söderling <i>[Signature]</i>							
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Swedish Patent Office	Sune Söderling <i>[Signature]</i>																